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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/707,852	11/07/2000	Andrey Zarur Jury	S1417/7004	9828

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EXAMINER

REDDING, DAVID A

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

09/707,852

JURY ET AL.

Examiner

Art Unit

David A Redding

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 156-173 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 156-173 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. In response to the restriction requirement filed 6/9/2004, applicant cancelled all pending claims and filed new claims 156-173.

Claim Rejections - 35 USC § 112

2. Claims 156-173 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims (#156) now specify a system comprising a reactor comprising a plurality of reactions units, each reaction unit having a chamber which has a surface suitable for cell growth, a volume of less than 1ml, and a membrane defining at least one wall of the chamber, the membrane being able to transport oxygen; the reaction units further comprising a gas enclosure positioned proximate the chamber for facilitating oxygen transfer. Applicant alleges support for this claim throughout the specification and specifically "page 7, lines 6-19; page 10, lines 2-19; page 11, lines 9-14; or page 12, lines 16-20. However, nowhere in the specification, including the specific locations cited by applicant, is there described an embodiment in which a chamber having a surface suitable for cell growth includes an oxygen-permeable membrane defining at least one wall of the chamber. Moreover, the specification does not include an original description of a gas enclosure positioned proximate the reaction chamber for facilitating oxygen transfer across the membrane (cl.

156, last paragraph). The claimed reaction chamber is specifically described in the specification on pages 9-10 and referred to in figure 5 as element (16). The specification specifically describes the reaction chamber,

"[I]n this unit, oxygen and nutrients are diffused from the flowing stream to the immobilized cells. The cells, in turn metabolize the feed, and produce proteins which are swept away in the flowing stream. The flowing stream enters the fourth chamber which removes the protein product from the solution." (page 10, lines 23-26).

There is no mention of the reaction chamber (16) having an oxygen-permeable wall.

The only permeable membranes in which there occurs transport across the membrane is in the separation unit (18), shown in figure 6. And the description of these membranes is limited to the extraction of product. There is no description of oxygen transfer across the separation membranes (34,36). On the contrary, the specification teaches away from this embodiment,

"[C]arrier fluid outlet 82 can be made connectable to a recovery container for recycling of reaction carrier fluids. In the example of a microbioreactor, residual oxygen and nutrients are recovered from outlet 82 and recycled back into the feed for the process."(col.11, lines 27-30).

If the membranes were for facilitating oxygen transfer, there would be no "residual oxygen" recovered from outlet 82.

Therefore the current claimed subject matter is not supported in the specification as originally filed.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 156-173, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 156, applicant specifies that the "chamber being constructed and arranged to maintain and cultivate cells in culture for at least a period of time sufficient to generated a product resulting from interaction of the cells with oxygen and/or nutrients and/or other components,". It is indefinite from a reading of the specification what structural elements **of the claims** provides the cited function.

Specification

5. The disclosure is objected to because of the following informalities: page 11, line 10, "[M]embranes 30", should be [M]embranes 34.

Appropriate correction is required.

6. The amendment filed 8/6/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: claims 156-173 (see paragraph #2 above).

Applicant is required to cancel the new matter in the reply to this Office Action.

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Information Disclosure Statement


7. Some of the prior art cited by applicant is considered to be related to the claimed invention. However, none of the references alone or together teach or suggest the system defined in claim 156.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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